

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney of record Mr. S. Maurice Valla on May 21<sup>st</sup>, 2008.

The application has been amended as follows:

#### ***In The Claims***

Claims 4, 5, and 18-22 have been canceled by this Examiner's amendment.

Claims 1, 2, 10-17 and 24-29 have been amended by this Examiner's amendment, and are allowed as follows:

1. A solid dispersion comprising a poorly soluble bioactive compound, which has a solubility of less than 1 gram per liter in an aqueous environment, dispersed in a polymer matrix that comprises a first polymer comprising a copolymer of vinylpyrrolidone and vinylacetate, and a second polymer that has a dissolution profile associated with the creation of a micro-environment enhancing the dissolution of the bioactive compound in said aqueous environment, wherein said second polymer comprises a cationic polymer based on dimethylaminoethyl methacrylate and neutral methacrylic ester, and wherein said first polymer and said second polymer are present in a ratio of 70-80 percent by weight of said first polymer to 20-30 percent by weight of said second polymer.

2. The solid dispersion according to claim 1 wherein at least one of said first and said second polymers has a stabilizing effect on the bioactive compound in solution.

10. The solid dispersion according to claim 1 wherein the bioactive compound is a class II drug in the Biopharmaceutical Classification System.

11. The solid dispersion according to claim 1 wherein the bioactive compound is a class IV drug in the Biopharmaceutical Classification System.

Art Unit: 1651

12. The solid dispersion according to claim 1 wherein the aqueous environment is a gastro-intestinal fluid.

13. The solid dispersion according to claim 12 wherein the aqueous environment is a gastric fluid.

14. The solid dispersion according to claim 1 prepared by extrusion.

15. The solid dispersion according to claim 1 prepared by spray-drying.

16. A solid dispersion according to claim 1 wherein the first polymer allows a homogenous or molecular dispersion of the bioactive compound in the polymer matrix, and wherein said first polymer and said second polymer are present in a ratio of 70:30 percent by weight.

17. The solid dispersion according to claim 16 wherein at least one of said first and said second polymers has a stabilizing effect on the bioactive compound in solution.

24. The solid dispersion according to claim 16 wherein the bioactive compound is a class II drug in the Biopharmaceutical Classification System.

25. The solid dispersion according to claim 16 wherein the bioactive compound is a class IV drug in the Biopharmaceutical Classification System.

26. The solid dispersion according to claim 16 wherein the aqueous environment is a gastro-intestinal fluid.

27. The solid dispersion according to claim 16 wherein the aqueous environment is a gastric fluid.

28. The solid dispersion according to claim 16 prepared by extrusion.

29. The solid dispersion according to claim 16 prepared by spray-drying.

The following is an examiner's statement of reasons for allowance:

Applicant's arguments regarding the unexpected results (see response, page 10, in particular) for the polymer matrix comprising a combination of two different polymers (i.e. "a copolymer of vinylpyrrolidone and vinylacetate" and "a cationic polymer based on

Art Unit: 1651

dimethylaminoethyl methacrylate and neutral methacrylic ester"; see instant claim 1, as currently amended) used to stabilize the composition (i.e. the solid dispersion comprising a poorly soluble bioactive compound as defined in instant disclosure; see page 5, line 5 and 6, and figure 13, in particular) as claimed (i.e. in the particular weight ratio for the two polymers, as claimed), is found to be persuasive and unobvious over the teachings of the cited prior art relied upon in the obviousness rejection of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sandra Saucier/  
Primary Examiner, Art Unit 1651

/Satyendra K. Singh/  
Examiner, Art Unit 1657